



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0449]

Agency Information Collection Activities; Proposed Collection; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the-Counter Sunscreen Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Sun Protection Factor (SPF) labeling and testing requirements for over-the-counter (OTC) sunscreen products containing specified ingredients and marketed without approved applications, and on compliance with Drug Facts labeling requirements for all OTC sunscreen products.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

SPF Labeling and Testing Requirements for OTC Sunscreen Products Containing Specified Active Ingredients and Marketed Without Approved Applications, and Drug Facts Labeling for All OTC Sunscreen Products--21 CFR 201.327(a)(1) and (i), 21 CFR 201.66(c) and (d)
(OMB Control Number 0910-0717)--Extension

In the Federal Register of June 17, 2011 (76 FR 35620) we published a final rule establishing labeling and effectiveness testing requirements for certain OTC sunscreen products containing specified active ingredients without approved applications (2011 sunscreen final rule; § 201.327 (21 CFR 201.327)). In addition to establishing testing requirements, this sunscreen final rule lifts the delay of implementation of the prior 1999 sunscreen final rule (published May 21, 1999, at 64 FR 27666 and stayed December 31, 2001, 66 FR 67485) from complying with the 1999 labeling final rule (published March 17, 1999, 64 FR 13254) in which we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products in part 201 (21 CFR part 201). Specifically, the 1999 labeling final rule added new § 201.66 to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products. We specifically exempted OTC sunscreen products from complying with the 1999 labeling final rule until we lifted the stay of the 1999 sunscreen final rule. The 2011 sunscreen final rule became effective December 17, 2012, for sunscreen products with annual sales of \$25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than \$25,000 when we published an extension date notice on May 11, 2012 (77 FR 27591).

SPF Labeling and Testing for OTC Sunscreens Containing Specified Active Ingredients and
Marketed Without Approved Applications

In the Federal Register of June 17, 2011 (76 FR 35678), we published a 60-day notice requesting public comment on the proposed collection of information in regard to SPF labeling and testing requirements for OTC sunscreen products containing specified ingredients and marketed without approved applications. In that notice, we stated that § 201.327 (a)(1) requires the principal display panel (PDP) labeling of a sunscreen covered by the 2011 final rule to include the SPF value determined by conducting the SPF test outlined in § 201.327(i).

Therefore, this provision results in information collection with a third-party disclosure burden for manufacturers of OTC sunscreens covered by the rule. We determined that products need only complete the testing and labeling required by the rule one time, and then continue to utilize the resultant labeling (third-party disclosure) going forward without additional burden. This one-time testing would need to be conducted within the first 3 years after publication of the 2011 final rule for all OTC sunscreens covered by that rule. We determined that the third-party disclosure burden by manufacturers of OTC sunscreens covered by the rule was based on an estimate: (1) Of the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information; (2) on the conduct of SPF testing based on the estimated number of existing formulations; (3) of the time to relabel currently marketed OTC sunscreens containing specified ingredients and marketed without approved applications; and (4) on testing and labeling of new products introduced each year. The estimate for this burden in the 2011 60-day PRA notice was a total of 30,066 hours in years one and two and a total burden of 966 in each subsequent year.

All currently marketed OTC sunscreen drug products are required at this time to be in compliance with the SPF labeling requirements specified by the 2011 final rule. However, our original estimate included the burden of new products introduced each year. We estimated that as many as 60 new OTC sunscreen products stock keeping units (SKUs) may be introduced each year which will have to be tested and labeled with the SPF value determined in the test. We estimated that the 60 new sunscreen SKUs represent 39 new formulations. The burden for testing and labeling these formulations was estimated at 30 hours per year.

We have received no further comments on our estimate of burden for the collection of this information other than two comments (FDA-2011-N-0449-0002 and FDA-2011-N-0449-0003). These comments were already addressed in FDA's notice of "Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sun Protection Factor Labeling and Testing Requirements and Drug Facts Labeling for Over-the Counter Sunscreen Drug Products" published on May 9, 2012 (77 FR 27230).

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden¹

Activity	No. of Respondents	Number of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Conduct SPF testing in accordance with § 201.327(i) for new sunscreens	20	1.95	39	24	936
Create PDP labeling in accordance with § 201.327(a)(1) for new sunscreen SKUs	20	3	60	0.5 (30 min.)	30
Total					966

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Drug Facts Labeling for OTC Sunscreens

Because the 2011 final rule also lifts the delay of implementation of the Drug Facts regulations (§ 201.66) for OTC sunscreens, the rule also modifies the information collection associated with § 201.66 (currently approved under OMB control number 0910-0340) and adds

an additional third-party disclosure burden resulting from requiring OTC sunscreen products to comply with Drug Facts regulations. In the Federal Register of March 17, 1999 (64 FR 13254), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products, codified in § 201.66 (the 1999 Drug Facts labeling final rule). Section 201.66 sets requirements for the Drug Facts portion of labels on OTC drug products, requiring such labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Therefore, currently marketed OTC sunscreen products will incur a one-time burden to comply with the requirements in § 201.66(c) and (d). The burden was estimated in the 60-day PRA notice published in the Federal Register of June 17, 2011 (76 FR 35678) as 43,200 hours for existing sunscreen SKUs and 720 hours for new sunscreen SKUs.

The compliance dates for the 2011 final rule lifting the delay of the § 201.66 labeling implementation data for OTC sunscreen products were December 17, 2012, for sunscreen products with annual sales of \$25,000 or more and December 17, 2013, for sunscreen products with annual sales of less than \$25,000, respectively, when we published an extension date notice on May 11, 2012 (77 FR 27591). All currently marketed sunscreen products are, therefore, already required to be in compliance with the Drug Facts labeling requirements in § 201.66 and will incur no further burden in the 1999 labeling final rule. However, new OTC sunscreen drug products will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. In the 2011 60-day PRA, we estimated that as many as 60 new product SKUs marketed each year will have to comply with Drug Facts regulations. We estimated that these 60 SKUs would be marketed by 30 manufacturers. We estimated that approximately 12 hours

would be spent on each label, based on the most recent estimate used for other OTC drug products to comply with the Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. This is equal to 720 hours annually (60 SKUs \times 12 hours/SKU). We stated that we do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e). However, we took this into consideration in 2013 and estimated the burden for an exemption or deferral by considering the number of exemptions or deferrals we have received since publication of the 1999 final rule (one response) and estimating that a request for deferral or exemption would require 24 hours to complete. Multiplying the annual frequency of response (0.125) by the number of hours per response (24) gives a total response time for requesting an exemption or deferral equal to 3 hours.

We estimate the burden of this collection of information as follows:

Table 2.--Estimated Annual Third-Party Disclosure Burden¹

Activity	No. of Respondents	Number of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Format labeling in accordance with § 201.66(c) and (d) for new sunscreen SKUs	20	3	60	12	720
Request for Drug Facts exemption or deferral § 201.66(e)	1	0.125	0.125	24	3
Total					723

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.